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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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SHELLEY P M FUSSEY
WILLIAMS MORGAN & AMERSON PC
7676 HILLMONT
SUITE 250
HOUSTON, TX 77040

EXAMINER

SHARAREH, SHAHNAM J

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 10/22/2002

32

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/351,149

Applicant(s)

THORPE ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 and 43-50 is/are pending in the application.
- 4a) Of the above claim(s) 10-15, 20-23 and 44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 16-19, 24-32, 43 and 45-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 10-15, 20-23 and 44 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>25, 29-31</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Amendment filed on June 20, 2002, Paper No. 27 has been entered. Claims 1-32, 43-49 are pending.

Claims 10-15, 20-23, 44 are withdrawn from further consideration, as being drawn to a nonelected species. Applicant timely traversed the restriction (election) requirement in Paper No. 15. This application contains claimed 10-15, 20-23, 44 drawn to an invention nonelected with traverse in Paper No. 14. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP. 821.01.

Claim 32 is free of art.

Correction of Inventorship

Declaration by the actual inventors as set forth in 37 CFR 1.48 (a) for correction of inventorship is received. The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the correct inventorship.

Response to Amendment

Any rejection that is not addressed in this Office Action is considered obviated in view of the Amendments and Arguments.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2-9, 14 stand rejected under 35 U.S.C. 102(e) as being anticipated by Schroit US Patent 6,300,308.

Applicant's arguments with respect to this rejection have been fully considered but they are not persuasive.

The instant claims are directed to kits containing at least a first aminophospholipid targeting agent-therapeutic agent construct in combination with a targeting agent-detactable agent or anticancer agent. This claim is not limited to two distinct constructs as the second anticancer agent encompasses any anticancer agent. Thus, the claims stand rejected for the reasons of record.

Applicant argues that the present kits are not directed to phosphatidylserine-polypeptide conjugates. However, such conjugates are within the scope of an anticancer agent (see Schroit, claim 21).

Applicant also asserts that the Action's reference to antibody directed to "aminophospholipid receptors" is not understood. Examiner points out that Schroit teaches PS specific antibodies that can be conjugated with a polypeptide. Since, PS is an aminophospholipid, Schroit's antibodies are directed to aminophospholipid receptors.

Applicant asserts that Schroit teaches immunodetection reagents alone and there is no reference to any therapeutic agent. Examiner disagrees with Applicant's interpretation of Schroit. Col 7, line 67- col 8, line 1, states "In such cases, one or more containers would contain each of the PS composition(s)." Therefore, Schroit's discloses kits that can contain containers with a second anti-aminophospholipid antibody conjugate. Further, Schroit claims an antibody-therapeutic construct (see claim 21). Moreover, Schroit's antibody can exist in "separate moieties to be conjugated by user of

the kit" (see col 6, lines 50-51). Thus, Schroit teaches PS antibody compositions are not only naked, but also can be used in combination with a therapeutic agent.

Applicant argues that diphtheria toxoid of Schroit is a carrier for lipid immunization. In response, Examiner states that regardless of the intended use, diphtheria toxoid of Schroit provides therapeutic activity within the scope of the instant claims. Accordingly, Schroit anticipates the limitations of the instant claims.

Claims 1-9, 16-19, 24-32, 43, 45-50 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Schroit US Patent 6,300,308 in view of Gimbrone US Patent 5,632,991, and Blackenberg et al US Patent 6,197,278.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, the combined teachings of cited references render the limitations of the instant claims obvious.

First, Examiner disagrees with Applicant's interpretation of Schroit. Col 7, line 67- col 8, line 1, states "In such cases, one or more containers would contain each of the PS composition(s)." Therefore, Schroit's suggests kits that can contain containers with a second anti-aminophospholipid antibody conjugate.

Further, applicant's assertion that the present kits are not phosphatidylserine-polypeptide conjugates are not persuasive, because the instant therapeutic constructs

within the kits do not exclude such constructs as taught by Schroit. Thus, Applicant's arguments are not commensurate with the scope of the claims.

In addition, Gimbrone and Blackenberg provide for a second anticancer agent or therapeutic construct. Therefore, all the limitations of the instant claims are taught.

Finally, the rejection is based on the combination of the teachings set forth in the cited references. Each reference is directed to specific receptor molecule on the surface of human vascular endothelial cells associated with vascularized tumor. Thus, they are viewed to be in the same field of endeavor and are considered combinable. Moreover, the compositions of Schroit, Gimbrone and Blackenberg are used for the same purpose. Accordingly, combining the compositions taught by each reference in order to form third composition that is to be used for very same purpose is *prima facie* obvious. see *In re Kerkhoven*, 205 USPQ 1069(CCPA) 1980. Therefore, claims stand rejected.

Claims 1-9, 16-19, 24-32, 43, 45-50 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over pending claim of copending Application No. 09/351862 ('862). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both directed to kits comprising antibodies directed to aminophospholipids and a second anti cancer agent.

Applicant argues that application '862 is directed to naked or "unconjugated antibodies" and the present kits are directed to "conjugated" therapeutic constructs. Nevertheless, the scope of the instant claims overlap with the scope of the pending application '862. Contrary to Applicant's statement, claims of '862 are not limited to only

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unconjugated antibodies neither are the instant claims limited to only conjugated therapeutic constructs. First, the language in both sets of claims is inclusive. For example, the claims of '862 are directed to "a kit comprising, in a pharmaceutically acceptable form, biologically effective amounts of at least a first anti-cancer agent, wherein said at least a first anti-cancer agent is at least a first antibody...". The instant claim 1 contains "a first antibody.,," thus, the instant claims teach the limitations of the claims in application '862.

Moreover, the instant anticancer agent encompass detectably-labeled antibody of '862. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to practice the claims in '862 application when in possession of the instant claims.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

ss
October 20, 2002


RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200